BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

As rescanning documents *will not* correct images, please do not report the images to the Image Problem Mailbox.

N.K.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/704,299	11/01/2000	John R. Bianchi	RTI-106	2390

7590 02/21/2003

VAN DYKE & ASSOCIATES, P.A.
1630 HILLCREST STREET
ORLANDO, FL 32803

EXAMINER	
PHILOGENE, PEDRO	
ART UNIT	PAPER NUMBER
3732	

DATE MAILED: 02/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

N.K.

Office Action Summary	Application No. 09/704,299	Applicant(s) BIANCHI ET AL.	
	Examiner Pedro Philogene	Art Unit 3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 November 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *04* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Continued Prosecution Application

The request filed on 2/28/02 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/704,299 is acceptable and a CPA has been established. An action on the CPA follows.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> **The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.**

Claims 6, 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 6, 7, line 1, the term "said wedge shape" lacks prior antecedent.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> **A person shall be entitled to a patent unless –**
>
> **(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.**

Claims 1-4, 9, 17-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Boyle et al. (6,277,149).

With respect to claim 1, Boyle et al. disclose a biomedical implant (10) designed for implantation into a spine of a patient comprising an elongated body (12) having first and second ends (FIG.1), the elongated body being tapered such that tapering begins

at a first position on or proximate to the first end and continues down the length of the elongated body down to a second position on or proximate to the second end; as best seen in FIGs.1, 3, 9; wherein the implant is comprised of cortical or cancellous bone; as set forth in column 2, lines 40-45.

With respect to claims 2-4, 9,17-19 Boyle et al discloses all the limitations, as set forth.

With respect to claims 20-23, the method steps, as set forth, would have been inherently carried out in the operation of the device, as set forth above.

Claims 15,16 are rejected under 35 U.S.C. 102(e) as being anticipated by Rainey et al (6,111,164).

With respect to claims 15,16, Rainey et al. disclose a method of producing a biomedical implant (10) that comprises an elongated body (12) having first and second ends (FIG.1) wherein the first end comprises two or more oblique sides (18), the method comprising obtaining a bone having a ridge naturally formed thereon and excising bone block sections from the bone at an angle substantially perpendicular to the ridge; as best seen in FIGS. 2A-2C; and as set forth in column 2, lines 57-67 and column 3, lines 1-15.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyle et al. (6,277,149) in view of Rainey et al. (6,111,164).

With respect to claims 5-8, it is noted that Boyle et al did not teach of a of an implant defining a wedge shape and having pinch cuts out in the first end formed thereon; as claimed by applicant. However, in a similar art, Rainey et al. evidence the use of a dowel with pinch cut outs in the first end, defining a wedge edge to facilitate the positioning of the dowel into a bone opening for grafting.

Therefore, given the teaching of Rainey et al, it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the wedge shape of Rainey et al in the device of Boyle et al., to facilitate the positioning of the dowel into a bone opening for grafting.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boyle et al. (6,277,149) in view of Branch et al (6,174,311).

With respect to claim 10, it is noted that Boyle et al. did note teach of an implant having a peg portion in the first end to engage a securing device, as claimed by applicant. However, in a similar art, Branch et al, column 10, lines 48-65, evidence the use of peg portion for securely engaging a tool holder.

Therefore, given the teaching of Branch et al, it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the peg portion of Branch et al in the device of Boyle et al for securely engaging a tool holder.

Claims 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyle et al. (6,277,149) in view of Paul et al (6,258,125).

With respect to claims 11-14, it is noted that Boyle et al teach all the limitations, except for an implant comprising two separate sections, as claimed by applicant. However, in a similar art, Paul et al, as best seen in FIGS 7,9,11, and column 4, lines 40-57, evidence the use of an implant having two separate sections to allow smaller sections of allergenic bone to be used for the fabrication of an implant.

Therefore, given the teaching of Paul et al, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the method of Paul et al to fabricate the device of Boyle et al to allow smaller sections of allergenic bone to be used for the fabrication of the implant.

Drawings

Color photographs and color drawings are acceptable only for examination purposes unless a petition filed under 37 CFR 1.84(a)(2) or (b)(2) is granted permitting their use as formal drawings. In the event applicant wishes to use the drawings currently on file as formal drawings, a petition must be filed for acceptance of the photographs or color drawings as formal drawings. Any such petition must be accompanied by the appropriate fee as set forth in 37 CFR 1.17(i), three sets of drawings or photographs, as appropriate, and an amendment to the first paragraph of the brief description of the drawings section of the specification which states:

> **The file of this patent contains at least one drawing executed in color. Copies of this patent with color drawing(s) will be provided by the Patent and Trademark Office upon request and payment of the necessary fee.**

Color photographs will be accepted if the conditions for accepting color drawings have been satisfied.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

5,609,636	3-1997	Kohrs et al.
5,593,409	1-1997	Michelson
6,165,219	12-2000	Kohrs et al.

This is a continuation of applicant's earlier Application No. 09/704,299. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pedro Philogene whose telephone number is (703)

308-2252. The examiner can normally be reached on Monday to Friday 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P Shaver can be reached on (703) 308-2582. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 305-3591 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Pedro Philogene
February 19, 2003

PEDRO PHILOGENE
PRIMARY EXAMINER